Lyoprotect® – The key to safe lyophilization

Lyoprotect® Single-use Tray with Filler Assembly

For freeze-drying pharmaceutical APIs. Simple handling and optimum protection of product and working environment.

✓ Simple handling

The filler assembly makes filling and closing the Lyoprotect® Single-use Tray really easy. An elaborate cleaning process is not necessary, as the tray is a single-use product. Thanks to the solid bottom, no transport sheet is required. Preliminary freezing in a deep freezer is possible.

✓ Safe sublimation

During sublimation, the vapor escapes via the hydrophobic membrane. It acts as a sterile barrier and protects the API (Active Pharmaceutical Ingredient) against contamination and the working environment and staff against fly-out. The membrane is firmly welded to a PP (polypropylene) tray. The filler assembly is also welded to the membrane.

✓ Easy filling

The Lyoprotect® Single-use Tray is filled via a funnel or tube, which is inserted into the filler assembly neck.

✓ Safe closure

The cap of the filler assembly is hand-screwed without any tools. Holding the retaining tab relieves the load on the weld seam when the cap is screwed on. Afterwards, the tray can safely be moved to the freeze-drier.

✓ Sterilization

The Lyoprotect® Single-use Tray can be sterilized in an autoclave by up to 121°C (250°F) for 20 minutes. It must be placed on the edge for sterilization, a slight distortion of the tray is possible. The cap must be open during the sterilization process. Sterile trays available on request.

✓ Fast removal

To remove the product, cut the membrane at the inner edge of the tray with a scalpel or cutter knife. Alternatively, cut off one edge and peel off the membrane by means of a spatula or folding tool.

Functional claims

- Bacteria-proof container with vapor-permeable membrane
- High sublimation rate
- No fly-out
- No cross-contamination
- Preliminary freezing is possible
- Safe compliance with occupational exposure limits (OEL 100 ng/m^3) with flexible isolators

Components of the Single-use Tray

Lyoprotect® Membrane:

- Expanded PTFE on non-woven polypropylene backing
- Firmly welded to PP tray

PP Tray:

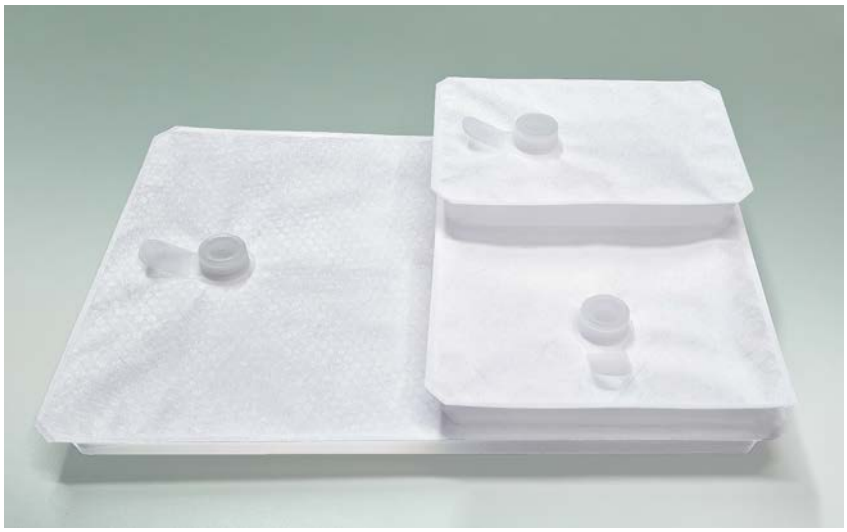
- Polypropylene tray, medical grade

Filler assembly:

- Firmly welded to membrane
- PP (polypropylene), pharma grade
- Opening of filler assembly: Ø 21.5 mm; suitable for tubes with approx. D_o ¾ inch or 20 mm
- Non-slip retaining tab

Quality claims

- 100% visual inspection of membrane and components
- Receiving inspection with FTIR spectrometer and full traceability
- BSE/TSE safe
- Complies with (EU) No 10/2011 regarding food safety
- Lot release tests
- On request: endotoxin test, extractables profile, toxicological evaluation
- Made in Germany



Lyoprotect® Single-use Tray, standard sizes

Filler assembly with retaining tab and screw-on cap

Dimensions

The Lyoprotect® Single-use Tray is offered in the following sizes. Individual dimensions available on request.

Order no.	dimensions W x L x H**	filling volume	filling level
LPSU-T1522-FA0909*	150 x 225 x 50 mm	230–570 ml	10–25 mm
LPSU-T1623-FA0009*	160 x 235 x 50 mm	230–570 ml	10–25 mm
LPSU-T2230-FA0909*	225 x 300 x 50 mm	500–1,300 ml	10–25 mm
LPSU-T2331-FA0009*	235 x 310 x 50 mm	500–1,300 ml	10–25 mm
LPSU-T3045-FA0909*	300 x 450 x 50 mm	1,100–2,800 ml	10–25 mm
LPSU-T3146-FA0009*	310 x 460 x 50 mm	1,100–2,800 ml	10–25 mm

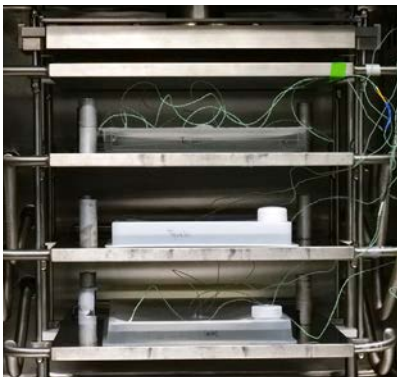
*The last 4 digits reflect the position of the filler assembly and the orientation of the retaining tab. Individual solutions possible upon request.

** Height incl. screwed-on cap. Edge height of tray: 30 mm.

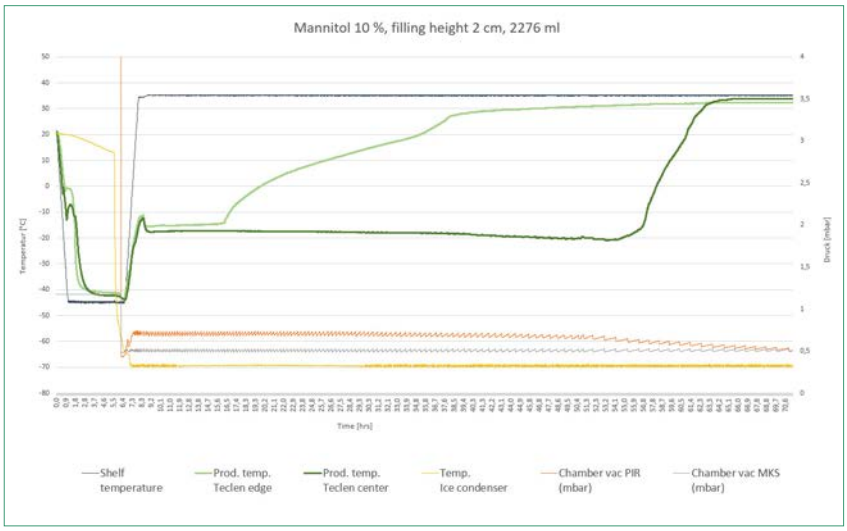
Product validation

Validation runs in Lyoprotect® Single-use Tray under the following conditions:

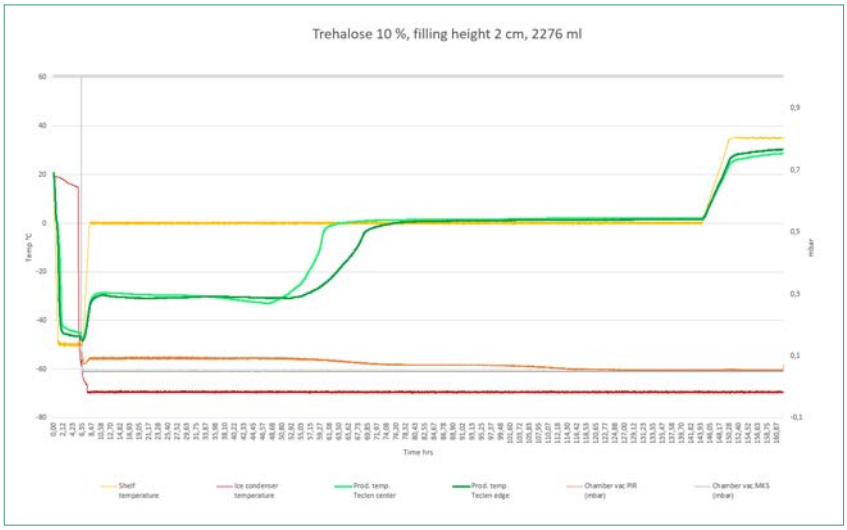
Validation runs with:	mannitol	trehalose
Concentration	10 %	10 %
Freezing	-45 °C	-50 °C
Vacuum	0.5 mbar	0.05 mbar
Primary drying	35 °C	0 °C
Secondary drying	35 °C	35 °C



Arrangement in freeze-drier
for validation run



Mannitol 10 %
residual moisture, center: 5 % ± 0.1 %
(SD n=2)



Trehalose 10 %
residual moisture, center: 0.9 ± 0.1 %
(SD n=2)

Lyoprotect® Product Overview – Bulk

Properties	Cup VXS	Cup VS	Stainless Steel Tray	Aluminum Tray	Open Tray	Single-use Tray	Tyvek® Tray	Bag DF	Membrane
	stainless steel	stainless steel	1622B	VM	stainless steel*	T1522-FA	2740-PE	w/o storage	w/o filler assembly
	aluminum		2740B		PP**	T2230-FA		with storage	with filler assembly
						T3045-FA			
Material	1.4404 (ANSI 316L) AlMg 4,5 MN	1.4404 (ANSI 316L)	1.4404 (ANSI 316L)	AlMg 4,5 MN	1.4404 (ANSI 316L) PP	ePTFE + PP	HDPE	ePTFE + PP	ePTFE
Filling volume	10–50 ml	30–150 ml	100–500 ml 400–1,800 ml max. 6,000 ml	100–500 ml	*indiv. sizes **see single-use tray	230–570 ml 500–1,300 ml 1,100–2,800 ml	400–2,000 ml	50–350 ml	
Customizable in size			✓		✓	✓		✓	✓
Multiple-use product	✓	✓	✓	✓	(✓)				
Sterilization methods									
Autoclaving	✓	✓	✓	✓	✓	✓	✓	✓	✓
Gamma sterilization							✓		
Handling									
Easy filling	●●	●●	●	●	●●	●●●	●●●	●●● 3)	●●● 3)
Easy removal	●●	●●	●	●	●●	●	●	●●● 2)	
Robustness	●●●	●●●	●●●	●●	●●	●●	●●	●	●●
Functionality									
Sterile barrier	●●● 1)	●●● 1)	●●● 1)	●●● 1)	●●● 1)	●●●	●●●	●●●	●●●
Preliminary freezing	●●●	●●●	●●●	●●●	●●	●●●	●	●	●●●
Storage	●	●	●	●	●	●	●	●●● 2)	●
Stackable (without rack)	●	●	●●●	●●●					
Performance									
Heat transfer shelf/container bottom	●●(●)	●●	●●	●●●	●●	●●	●●	●●●	
Fast drying	●●●	●●●	●●●	●●●	●●	●●	●	●●●	●●●
Incoming goods inspection									
Endotoxine pre-sterilization						✓			✓
Surface roughness	(✓)	✓	✓						
FTIR spectrometry						✓		✓	✓
Lot release test									
Seam strength/tightness						✓	(✓)	✓	
Tightness test			✓			✓	(✓)	✓	
100 % control for visible particles	✓	✓	✓	✓	✓	✓	(✓)	✓	✓
Biocompatibility, food contact, pharmacopeia									
Food contact U.S. / EU	✓	✓	✓	✓	✓	✓	✓	✓	✓
TSE/BSE safe	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tests for sub-visible particles (SVP) acc. to USP 788; EP 2.9.19						on request		on request	on request

● acceptable ●● good ●●● best 1) with bag/membrane 2) with storage 3) with filler assembly

All technical information and recommendations are based on our experiences and / or test results. They are given to the best of our knowledge, but do not state any liability by our company. Users are responsible for checking the suitability of the respective product for their specific application.

Teclen

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You can find detailed order information in the Teclen® Lyoprotect® product catalog

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